



Health  
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# **Health Protection Legislative Renewal Workshops**

**on**

## **Advertising**

**A Report on Stakeholder Consultations in Montreal, Toronto and Ottawa**

**Final Report**

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## EXECUTIVE SUMMARY

In fall 2003, Health Canada conducted consultations with a broad range of stakeholders focusing on advertising of health products as outlined in the proposed new Canada Health Protection Act. Community and consumer groups, patient groups, academia, industry, media, and health professional associations from across the country attended three two-day workshops, held in Montreal, Toronto and Ottawa. More than 70 participants brought extensive experience and expertise to these discussions.

The workshops were organized by Health Canada's Office of Consumer and Public Involvement, Office of Regulatory and International Affairs, and Legislative Renewal Secretariat, in conjunction with Intersol, an Ottawa-based communications and facilitation company.

The agenda covered the following topics:

- Deception
- Direct-to-consumer advertising
- Schedule A
- Distribution of samples
- Health practitioner oriented promotion.

Overall, many participants oppose any form of advertising for prescription drugs, while others think that it should be allowed with tight controls.

While achieving consensus was not the objective of the consultations, participants did agree on several overarching points, as follows:

- **The status quo is not tenable.** Existing provisions are out of date. Current sanctions are inadequate, as are monitoring and enforcement.
- **Better information is needed.** Consumers and practitioners need and deserve clear, balanced and neutral information in order to make informed choices about their health or that of their patients. Information should be based on valid data and presented in a balanced manner with adequate reference to the benefits and risks. Many participants considered that advertising is not information since its purpose is to promote sales.
- **Greater control is needed.** Greater control is needed over advertising than presently exists. However, there are differences over what advertising to control and how. Canada should not follow the U.S. model but requires a solution adapted to the needs of Canadians. If drug advertising is allowed, it should be subject to meaningful controls including pre-clearance of the proposed promotion.
- **Health and safety is the highest priority.** The priority of any new health protection legislation must be the health and safety of Canadians. If and when advertising is allowed, it should be controlled and restricted to ensure that it contributes to the health and safety of Canadians.
- **There is an important role for Health Canada.** Health Canada must maintain a strong role in setting policy and guiding legislation.

Participants also identified elements of the approach that Health Canada should take as it develops its legislative proposal and associated regulations pertaining to advertising, including:

- **Clarify and tighten definitions**, such as deception, monitoring, enforcement, advertising, promotion, sampling and health practitioner.
- **Role for independent third party bodies.** Many participants see a role for independent bodies in overseeing key aspects of Advertising of health products. These bodies must be balanced overall, and include consumer as well as health practitioner representation.
- **Monitor and enforce.** Participants want to ensure that any new legislation and regulation will include clear and effective enforcement mechanisms with meaningful sanctions.
- **Transparency is essential.** There is a need for transparency in the development and dissemination of information, as well as regarding compliance and enforcement.

With respect to the legislative proposal and its provisions pertaining to advertising, participants called for the proposed legislation to:

- **Address general concerns:** Monitoring and enforcement capacities and resources were identified as a key concern. Participants also cited concerns about vulnerable populations. Many concerns focus on definitional issues such as “deception”, valid data,” “health product,” and “promotion.”
- **Eliminate deception.** Participants agree with the intent of the proposal on deception. They want less vagueness, greater clarity and valid data. They want to strengthen rather than weaken the current situation. There are also divergent views regarding where the burden of proof should lie, and which body should be mandated to carry out monitoring and enforcement activities.
- **Develop a solution for drug advertising adapted to the Canadian situation and promote Direct-to-Consumer Information and Direct-to-Consumer Education (as opposed to advertising):** The current system is untenable. There was no agreement on whether or not to allow advertising for prescription drugs. Whichever tool is used to control Direct-to-Consumer Advertising (DTCA), it should ensure access to balanced information based on valid data for health practitioners and for consumers. Participants also support effective, transparent and timely monitoring and enforcement. However, there were divergent views about controls and whether controlled advertising/promotion is only marketing or whether it could be one mechanism to disseminate information.
- **Adapt Schedule A.** Most participants agree that Schedule A must be retained and reinforced. However, it needs updating, along with clear criteria and a transparent process for doing so. Participants feel that updating should be undertaken by an independent and broad-based advisory committee which includes consumers and health practitioners. However, there were divergent views about the criteria and process for updating Schedule A and the appropriate body to oversee this.

- **Regulate Sampling.** While there was no agreement about whether or not sampling should be allowed, all participants agree that if it were allowed, some controls and restrictions would be necessary. Participants did not reach agreement about whether or not sampling should continue to be allowed to health practitioners or whether some sampling should be allowed directly to the public. If the distribution of samples to health practitioners continues, controls and restrictions are needed. Moreover, participants agree that the definition of sample needs to be clarified, in the context of the definitions of advertising and promotion, although there was no agreement about how it should be defined and by whom.
- **Control health practitioner oriented promotion.** Participants expressed divergent views about whether promotion to health practitioners should be permitted. There was general support for distinguishing between promotion and information/education and controlling the content. Controls could take the form of a code of conduct with a set of binding rules that should be monitored and enforced, and perhaps pre-cleared by an independent body.

# 1. INTRODUCTION

## 1.1 Background to consultations

In fall 2003, Health Canada conducted consultations with a broad range of stakeholders focusing on advertising of health products as outlined in the proposed new Canada Health Protection Act.

The current legislative renewal consultations build on consultations conducted in 1998 and 1999 on broad issues related to health protection. At that time, the focus was on developing guiding principles for a revised regulatory framework for direct-to-consumer advertising of prescription drugs.

Participants identified the following objectives for the provision of drug information to the consumer:

- Ensuring consumer safety
- Assisting consumers in making informed choices
- Respecting the health care practitioner
- Addressing health care costs
- Ensuring accountability
- Acknowledging the Canadian environment.

The ensuing report also identified health protection areas that were of particular concern to the public.<sup>1</sup> That input has guided the development of a new legislative framework for federal health protection laws centered on a new Canada Health Protection Act. The Legislative Renewal Consultation Process is underway to obtain the views of the public on a detailed proposal.

## 1.2 Consultations on Advertising

Advertisement, as defined under the *Food and Drugs Act and Regulations*, includes “any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device.”<sup>2</sup>

The purpose of these particular consultations was to talk with a diverse group of informed stakeholders about several issues related to the advertising of health products: Deception, Direct-to-Consumer Advertising, Schedule A (a list of diseases for which advertising is currently prohibited), Distribution of Samples and Health Practitioner Oriented Promotion.

Over 70 stakeholders were invited to three two-day workshops - one in Montreal, Toronto, and Ottawa in late November and early December. The stakeholders represented community and consumer groups, patient groups, academia, industry, media, and health professional associations.

A team of Health Canada staff was present in each location to present relevant information related to the new proposal and listen to participants. The agenda for the workshops allowed ample time for small group discussion with reports to plenary on each topic. The agenda was developed by the Office of Consumer and Public Involvement, the Office of Regulatory and International Affairs and the

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<sup>1</sup> For information on earlier consultations on direct-to-consumer-advertising, see [http://www.hc-sc.gc.ca/hpfb-dgpsa/oria-bari/as\\_said\\_e.pdf](http://www.hc-sc.gc.ca/hpfb-dgpsa/oria-bari/as_said_e.pdf) (1998 report) and [http://www.hc-sc.gc.ca/hpfb-dgpsa/oria-bari/dtca\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/oria-bari/dtca_e.html) (1999 report). See also <http://renewal.hc-sc.gc.ca> for information on the current legislative renewal process and relevant documents.

<sup>2</sup> *Detailed Legislative Proposal, ibid.* 2003, 79.

Legislative Renewal Secretariat, in conjunction with Intersol, an Ottawa-based communications and facilitation company.

Sessions were professionally facilitated by Intersol staff. Table discussions were facilitated by volunteer participants; notes were taken by Health Canada staff. Notes in plenary sessions were recorded by staff of Practicum Limited, Toronto-based consultation and facilitation specialists. This report on the workshops on advertising is based on notes from table note-takers and plenary notes for each session. It presents a synthesis of discussions on each topic, focusing on highlights which reflect themes, areas of convergence, issues and concerns, and key messages.

Please refer to “Appendix A” for workshop agenda and “Appendix B” for a complete list of participants.

## 2. DECEPTION

Deceptive health claims refer to misleading claims as they relate to health and safety. These would be prohibited under the new Act. The proposed Act would also require anyone making a health claim to have valid data to support it, and would place the burden of proof on the person making a claim to demonstrate its truthfulness<sup>3</sup>.

### 2.1 Areas of convergence

Participants agree on a number of key areas related to deception:

- **Avoiding deception is necessary for public safety.** In all three workshops, there was general agreement on the need for provisions on deception. Further, participants agree that provisions should focus on health protection, health and safety.
- **Terms must be clarified and better defined.** While participants recognize the challenge in establishing a suitable definition of deception, they agree that greater clarification is needed for a number of terms and concepts of deception. See below.
- **Deception is part of a continuum.** There is an overall sense that pre-clearance, deception and enforcement should be seen as a continuum, and that provisions must be developed with the entire continuum in mind.
- **There is a need for mandatory pre-clearance.** Participants feel that current enforcement and pre-clearance are inadequate. They see pre-clearance as necessary and want it to be mandatory. They agree that this requires high standards, well-trained personnel, effective and transparent monitoring, and effective sanctions.
- **There is a need for balanced, independent, plain language information.** There is full recognition that the public should have access to balanced information based on valid data from independent sources. Integral to this agreement is the understanding that Health Canada would pre-approve the summary of data for certain classes of products.<sup>4</sup>

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<sup>3</sup> *Detailed Legislative Proposal, ibid.*, 40

<sup>4</sup> *ibid* , provision B6.5, 41

It is also suggested that compliance would be more likely if principles were formulated based on balanced information and applied to all media. Thus, participants agree that there should be a body to vet advertisements to ensure that deception is not taking place. They also discussed the idea of having a body to ensure the accuracy of information contained in the advertisements; they did not agree, however, on where this body should reside.

- **Provisions must be comprehensive and flexible.** Participants on the whole, agreed that these provisions should apply to all media, although the Internet in particular, is of concern. They also advise that provisions should be sufficiently flexible to address any media that may be developed in the future.

## 2.2 Need for clarification

Participants suggested a number of terms requiring further clarification:

- **Deception.** Participants note that deception should be defined in terms of risk reduction, and in absolute rather than relative terms. The current definition does not deal with the absence of balanced information, such as side effects and therapeutic or non-therapeutic alternatives. It must also take into account the context for ads and consider all that the public is seeing and perceiving.
- **Health product.** The provisions must clarify what categories of products are included as well as excluded (prescription/non-prescription, and categories within non-prescription). Would the categories apply to all media? Current criteria for the application of provisions do not apply equally to all categories of products.
- **Promotion.** Participants are concerned that the provisions on deception, as currently formulated, do not clearly specify what constitutes promotion.
- **Education, information, advertising and promotion.** Participants highlight the need to distinguish among education, information, advertising and promotion.
- **Products as well as processes.** Currently, the provision covers only products. To help ensure that the public not be misled as to the characteristics, value, safety and effectiveness of health products, participants feel that the provision may need to apply to processes as well as products.<sup>5</sup>
- **Basis for “truthfulness”.** Participants note that truthfulness should be based on “burden of proof” and meaningful research, rather than “science and objective observation.” This concern deals with the nature of evidence itself.<sup>6</sup>
- **Validity.** In terms of valid data to support a claim, participants point to the need to be clear about what is considered valid, by whom, and by what method(s). They suggest that data must be independent and “evidence based”. There was some discussion on whether the evidence should be derived from real world experience or clinical trials.<sup>7</sup>

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<sup>5</sup> *ibid.*, B6.1, 40

<sup>6</sup> *ibid.*, B6.3, 40

<sup>7</sup> *ibid.*, B6.4, 41



- **Meaningful data.** When it comes to the requirement for the manufacturer to make a meaningful summary of supporting data available to the public, participants call for greater clarity of ‘meaningful’. They also question who would control the information that the manufacturer makes public.<sup>8</sup>
- **“Public media” and “Ought to have known”.** While some participants support the idea of making it an offence for public media to disseminate an advertisement it “knew or ought to have known” to be in contravention of the Act or the regulations, others are of the view that this is an unrealistic and impractical provision.<sup>9</sup> The expression, “public media,” is not clear, and some wonder whether it should also pertain to private media.

### 2.3 Issues

Over and above the broad areas of agreement and the call for greater clarity and definitions, participants identified several issues for further exploration, including:

- **Burden of proof.** There is general agreement that manufacturers must make available to the public a valid summary of data in support of a claim that relates to the safety of a product or its effect on health. However, some express concern that placing the burden of proof on the supplier would be unreasonable since the supplier may not have the capacity to independently determine whether information is balanced and based on valid data. Many parties feel that there should be pre-clearance by a body with access to such information. However, there is no agreement about the optimal body to perform this function.
- **Context.** Some participants suggest that information, in itself, may not be promotional but in a specific context it may be. Context, must, therefore, be considered in determining whether deception is taking place.
- **Monitoring and enforcement.** Participants feel that there are insufficient resources to monitor and enforce what Health Canada is currently mandated to do, and, therefore, suggest that the practicality of enforcement be integral to the development of provisions on deception.

There is agreement, however, that monitoring and enforcement must be properly resourced and strengthened, and must include:

- Proactive monitoring
- Immediate retraction
- Clear mechanism for dealing with violations, including need for corrective message.
- **Pre-clearance.** While there is disagreement over which body should be mandated to oversee pre-clearance, some participants suggest that a body with multi-stakeholder representation be enshrined in legislation and given adequate training. Participants also agree that pre-clearance of ads should not over-ride the pre-market authorization system.

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<sup>8</sup> *ibid.*, B6.5, p.41

<sup>9</sup> *ibid.*, B6.6, p.41

- **Vulnerable populations.** Some participants in all sessions expressed concern about the need to provide adequate protection for vulnerable populations.

## 2.4 Conclusions

In conclusion, participants agree with the intent of the proposals on deception. They want less vagueness and greater clarity. They have concerns about definitions, monitoring and enforcement. They want to strengthen rather than weaken the current situation.

## 3. DIRECT-TO-CONSUMER ADVERTISING (DTCA)

In the proposed legislation, restrictions would be imposed on the advertising of health products to consumers, by way of regulations (independent of the provisions pertaining to Schedule A, which is dealt with later in this report). Some of the tools to be used to design an appropriate scheme could include one or a combination of the following:

- Tool 1 - Prohibiting the promotion of prescription health products
- Tool 2 - Dissemination of consumer health product information
- Tool 3 - Controlling the content of the promotion
- Tool 4 - Pre-clearance<sup>10</sup>

Overall, many participants oppose any form of advertising for prescription drugs, while others believe it should be allowed with tight controls.

### 3.1 Tool 1 - Prohibiting the Promotion of Prescription Health Products

Opinion is divided on this tool. Participants highlight the following:

- **Advertising is misleading.** A number of participants favour Tool 1, because they believe that advertising is not information since its purpose is to promote sales. They consider that it manipulates the public and leads to patient-induced demand for therapies and drugs.
- **DTCA is already in Canada.** At the same time, participants recognize that DTCA, while illegal in Canada, already reaches Canadians from a variety of foreign sources, particularly the U.S. Moreover, most participants perceive that current regulations are not being adequately enforced.
- **Status quo is outdated.** The status quo - allowing the promotion of name, price and quantity – is outdated. Some participants express concern that many ads are pushing the boundaries of what is allowed in terms of help-seeking and reminder messages.
- **Health outcomes data is needed.** Participants note a need for data on the impact of DTCA on health outcomes, not only on sales. While substantial data exist, there was a call for Canada-specific, Canada-wide data.

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<sup>10</sup> *ibid.*, pp 86-92

In addition:

- Some believe that the distinction between over-the-counter and prescription drugs should be maintained; others do not.
- There was discussion but no agreement about whether to have an outright ban on specific brand advertising and allow only generic advertising.

### 3.2 Tool 2 - Dissemination of Consumer Health Product Information

There is overall consensus that this is a useful tool. Participants offer a number of suggestions for improving information and access to it:

- **Promote Direct-to-Consumer Information and Direct-to-Consumer Education (as opposed to advertising).** Many participants consider that advertising is not information since its purpose is to promote sales.
- **Clear, balanced and neutral information is needed.** There was much emphasis on the need for clear, balanced and neutral information in the discussion of this tool. Participants want objective information from an independent source or multiple sources. There is a need for a solution adapted to the Canadian situation. Information should include alternative therapeutic and non-therapeutic products, side effects, consult your doctor, and good lifestyle habits.

Participants suggest a neutral health information site, [www.drugsforyou.ca](http://www.drugsforyou.ca), for health practitioners and pharmacists. There could also be a 1-800 number to provide information. This effort should be complemented by a knowledge management strategy. There are divergent views about how the information should be funded. Options discussed include funding by pharmaceutical companies with input from government.

Some suggest that the information could be provided by Health Canada, with costs supported by industry as part of product assessment for advertising approval. Support might also come from federal and provincial governments.

There was some discussion of dissemination costs. Suggestions include profits from promotion, percentage of DTCA ads, Health Canada, and a partnership of consumers, industry and health professions.

- **International models are useful.** International models were noted, such as The Australian National Prescription Service, which can be useful in the Canadian discussion on DTCA.
- **Extend the product monograph model.** Some participants suggest that the product monograph model is helpful but are concerned that it does not go far enough. Information should be user-friendly, based on valid data and disseminated by either Health Canada or a third party. Ownership of monographs was also an issue with some participants suggesting that it should reside at Health Canada.

Some suggest class monographs rather than drug specific monographs to address health conditions rather than particular products.

Participants also noted a number of concerns:

- **Access to information is an issue.** Some participants are concerned about access to information for people without phone and computer and with low literacy levels. Some participants note the importance of providing information in languages other than English and French. And some caution considerations for both ends of the age spectrum: youth are more Internet savvy, and should also have exposure to health promotion information in schools; older generations tend to be more reliant on authority figures and more traditional forms of information.
- **Enforcement is needed.** Participants agree that current enforcement is inadequate and want to ensure that any additional enforcement responsibilities are appropriately supported.
- **Definition of health product.** Again, some question the definition of health product and whether it should apply to both prescription and non-prescription products. Some suggest the need to include any product with a health claim.
- **Roles.** Roles for Health Canada, academics, consumers, and community leaders need to be determined. There is a clear sense that Health Canada should set the guidelines and be accountable for ensuring that they are met.

### 3.3 Tool 3 - Controlling the content of the promotion

As noted earlier, some participants are firm in their view that advertising is marketing. These participants do not want any DTCA and thus do not see the need to discuss ways to control the content of any promotion. That being said, those who favour Tool 3 are in general agreement with its provisions, and raised a number of concerns to ensure its effectiveness:

- **Need to ensure effective implementation.** Participants are concerned about the need for resources for effective pre-clearance, and for monitoring and enforcement.
- **Control promotion, not information and education.** Pre-clearance should apply to both promotion and information. A number of participants are concerned about potential conflicts of interest between public health and promotion of health products.
- **Need stronger proposal.** Some participants believe that the proposal needs to be strengthened to minimize opportunities for self-diagnosis and treatment.
- **Review sections for universal applicability.** Most are of the view that the 12 proposed provisions in Tool 3 do not apply equally to all product classes.<sup>11</sup> Certain sections are suited to both prescription and non-prescription products, such as those dealing with pre-market approval claims, valid data, balanced representation, risks and benefits, comparisons, and adverse effects (B10.3.3.2.3.1-, 2, 4, 5, and 11). Others, such as those dealing with physicians' determination of forms of treatment and product monographs, do not apply to non-prescription products (B10.3.3.2.3.7 and .10); and, still others, such as the section dealing with comparison between health

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<sup>11</sup> *ibid*, 88-91. These provisions are intended to establish principles to help prevent the public from being misled.

products and information that may or may not be included in promotion (B 10.3.3.2.3.5 and .9) seem contradictory. It is necessary to review this section with a view to determining what belongs and what does not to each product class.

- **Assign product code.** To make information more accessible to the public across a variety of media and sources, it was suggested that products be assigned a code.
- **Develop a solution adapted to the needs of Canadians.** If drug advertising is allowed, it should be subject to meaningful controls including pre-clearance of the proposed promotion. This may include ensuring that a drug must be on the market for a determined amount of time before advertising is allowed. Messages would have to include reference to alternative treatments, “consult your doctor,” pros and cons, and risks and benefits. This needs to be done effectively and monitored.

### 3.4 Tool 4 - Pre-clearance

- **Pre-clearance is necessary.** Participants agree that pre-clearance should be mandatory and apply to both promotion and information. If “help-seeking” and “reminder” ads continue to be allowed, many suggest that they should be pre-cleared.
- **Health and safety are a priority.** Participants agree that health and safety take priority over economic and other interests. Fast tracking should not come at the expense of safety.
- **Role for independent third party bodies in pre-clearance.** There is wide support for pre-clearance by an independent, trustworthy third party, staffed by experts from different fields and informed by consumers.

Any third party body must be characterized by transparency, timeliness and responsiveness. Some used the example of the Pharmaceutical Advertising Advisory Board (PAAB), highlighting the need for multi-stakeholder composition, and a majority of non-pharmaceutical and independent voices to ensure balance.

Participants agree that clear criteria are required to determine what would constitute balanced information and valid data. Participants agree that Health Canada has a key role to play in setting policy and standards.

- **Capacity and resources are needed.** Again, there is concern about capacity and resources to ensure compliance and enforcement.
- **Clear authority is needed for sanctions.** Any pre-clearance mechanism must have the authority to levy sanctions and to report on violations to the public. Sanctions should be effective, transparent, and timely.

Again, there was some discussion of funding. Participants have divergent views about funding mechanisms. Some suggest user fees; others suggest that industry pay with profits from promotion with no control over content; others suggest a combination of government and user fees. Many expressed the view that money spent by manufacturers on advertising could be used to supply more balanced, accurate and neutral information to consumers and to health care practitioners.

### 3.5 Combining the tools

Participants put forward a range of solutions with respect to DTCA Tools.

**Tools 1 and 2.** Those opposed to DTCA favour Tool 1 (no promotion of prescription health products), with strengthened enforcement and monitoring. Many of those supporting this Tool 1 feel that that ‘reminder’ ads and ‘health seeking’ ads should not be allowed, and that Tool 1 would, therefore, be more effective in combination with Tool 2 (dissemination of consumer health product information).

**Tools 2, 3 and 4.** Many agreed that information could be more effectively disseminated using a combination of Tools 2, 3, and 4, which would respond to a wide spectrum of opinions.

### 3.7 Conclusions

While there are divergent views regarding the tools in the proposal, discussion highlighted the following areas of agreement:

- **Public safety is a priority.** Participants agree that any advertising of health products must place priority on public health and safety.
- **The current system is untenable.** There is general agreement that the current system is untenable. Overall, there is great concern about the nature of the information currently available and about its sources. It will be important, therefore, to have strong restrictions and controls, along with effective and transparent pre-clearance, monitoring and enforcement. However, there is no clear agreement as to the form that these controls should take, and who should oversee the controls. Regardless of whether it should be Health Canada or a multi-stakeholder independent organization, it must take consumer views into account.
- **Promote Direct-to-Consumer Information and Direct-to-Consumer Education (as opposed to advertising).** Participants agree on the importance of consumer access to balanced and valid information about health products in order to make informed decisions. While some participants feel that advertising can fulfill this function with tight controls, others oppose any form of advertising for prescription drugs.

**Information must be accessible.** Participants agree that information should be in plain language, user-friendly, and supported by adequate resources. And again, there is no agreement about the optimal body to manage the information. There is concern about how these activities would be funded.

Participants favour a range of options for dissemination of information, including:

- Public service announcements, building on the model of ParticipAction
- 1-800 numbers
- Websites.
- **DTCA and health practitioner oriented promotion are related.** Finally, DTCA cannot be separated from health practitioner oriented promotion. Prescribing practices need addressing, perhaps by developing guidelines/regulating to ensure effective prescribing.
- **Develop a solution adapted to the Canadian situation.** While we cannot escape the fact that United States ads are widely seen in Canada, participants clearly do not want the US model of drug

advertising. Many fear that these ads increase demand for, and consumption of, particular prescription drugs, and contribute to heightened medicalisation. Participants want citizens to be part of devising the solution.

#### **4. SCHEDULE A**

The legislative proposal presents three options for Schedule A. Discussion flowed back and forth among the three options:

##### **4.1 Option 1 - Keep a list of diseases for which advertising is not allowed, but have a clear set of criteria for determining which diseases should be listed**

There are a number of overall areas of agreement with respect to Option 1:

- **Schedule A needs updating.** There is agreement that Schedule A, as it currently exists, is outdated and incomplete. Some feel that it is no longer comprehensive or legitimate. It is seen to impede promotion of claims that have recognized public health benefits. Further, the process for modifying it is lengthy and cumbersome.
- **A process is needed for regular updating.** A clear updating process is needed and most feel that any changes should be made with the sole purpose of consumer safety.
- **Clear criteria are needed to ensure transparency.** Most agree that clear criteria are needed for including diseases and conditions on the list, as well as clear administrative guidelines. Many would like the schedule to include both physical and mental health conditions and, perhaps, some symptoms (arthritis, for example).
- **Responsibility should rest with an independent body.** Participants feel that updating should be undertaken by an independent and broad-based advisory committee, which includes consumers as well as health professionals. It is also important that the committee be accountable, though there was little time to discuss how and to whom.

##### **4.2 Option 2 - Retain Schedule A, but have some flexibility with respect to the type of claim which may or may not be allowed**

Again, there are a number of overall areas of agreement on Option 2:

- **DTCA requires Schedule A.** Schedule A, with the additional flexibility offered in Option 2, is preferred by some to Option 1 on the basis that it offers a safety net. Participants acknowledge the value of such provisions as pre-clearance, controlling the content of promotion and controls on deception. However, if such safety provisions are not properly implemented, monitored and resourced, Schedule A remains critical and essential.
- **Flexibility is needed.** Flexibility is considered important to reflect changes in the evidence base and to include mental health conditions and symptoms, as well as physical health conditions.

- **Schedule A must serve the public interest.** Some feel that promotion of preventative products, which serve the public interest, should be allowed; examples include sunscreen and condoms. At the same time, participants acknowledge the difficulty in defining the public interest.
- **Simple and timely updating mechanisms are needed.** Those favouring Option 2 recognize the need for simple, uncomplicated and timely updating mechanisms. Concerns remain about whether Health Canada has the capacity and resources for this.
- **An independent body is required.** As with Option 1, Option 2 would require an independent advisory committee to ensure that the process for establishing criteria and for making changes to Schedule A is transparent, rigorous and timely. Representatives on this committee should include not only scientific experts, but also consumers.

#### 4.3 Option 3 - Eliminate Schedule A altogether

There is no agreement with respect to the elimination of Schedule A.

- The fact that other sections of the proposal offer sufficient protections, was cited as the rationale for participants supportive of and opposed to eliminating Schedule A.
- Some participants indicate that they would support Option 3, if DTCA for prescription drugs is disallowed in the future. As with Option 2, participants note that, if DTCA is permitted, Schedule A is needed.
- Others feel that Option 3 could be acceptable under particular conditions, for example that products be subject to Tools 2, 3, 4 set out under DTCA, that products include innovative (and alternative) therapies and treatments, and that there be input from the provinces in helping to identify what can be advertised/promoted.

Participants raised two additional concerns in their discussion of Option 3:

- **Option 3 requires strong pre-clearance.** It was suggested that without Schedule A, all product information would require strong pre-clearance, indicated by a clear logo or identifier or identification number.
- **There are concerns for public health and safety.** There is considerable concern that, without Schedule A, consumers with serious diseases or conditions could self-diagnose and self-treat and, therefore, be at risk.

Participants reiterated earlier discussions about the need for information that is balanced, neutral, independent and broadly available, as well as the need for a body to produce or oversee the dissemination of such information. Again, participants made a number of suggestions for funding such a body, including:

- Creating a foundation or a fund for health promotion
- Establishing a Health Canada tax to fund development of credible reliable information rather than developing a complicated system of regulations
- Asking pharmaceutical companies to cost share for every dollar as the Canadian broadcasting industry does for Canadian content and other purposes.



#### 4.4 Conclusions

Most participants agree that Schedule A should be retained and reinforced (Option 1 or 2) rather than eliminated, and that clear criteria are needed for adding or removing diseases and conditions (as well as symptoms) from the schedule.

Participants expressed particular concern that the needs of vulnerable populations, including caregivers, must be taken into account. They are also concerned with how best to deal with products that they feel should not be advertised and which currently do not fall under Schedule A, such as infant formula.

Discussion of Schedule A also highlighted a number of more general concerns with respect to the proposal:

- The need to clearly distinguish what would be in the Act and what would be in regulations
- The need for clear definitions of many terms, including advertising, education, information, promotion, counseling, treatment, prevention, cure, and risk reduction.
- The need for legislation, regulation and claims to be based on sound clinical evidence of safety and effectiveness
- The existence of contradictions between provincial and federal jurisdictions, such as provincial recognition of alternative health practitioners and natural health products, which cannot be advertised according to the current legislation.

#### 5. DISTRIBUTION OF SAMPLES

The proposed legislation would establish regulation-making authority respecting the distribution of health products as samples. For example, regulations could provide for:

- Prohibition and guidelines on what constitutes sampling;
- Distribution to and by qualified health practitioners, with guidelines;
- Sampling non-prescription drugs contributing positively to public health;
- Distribution of cosmetic samples, including those with a public health benefit.<sup>12</sup>

##### 5.1 Option 1 Prohibit distribution of drug samples (both over-the-counter and prescription drugs) and establish guidelines regarding what constitutes sampling.<sup>13</sup>

A number of participants agree with this option and prefer no distribution at all, given the risk of allergic reactions and interactions.

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<sup>12</sup> *Ibid*, p.95

<sup>13</sup> Please note that the options set out in this section of the report do not precisely follow the legislative proposal. They were developed to capture the sense of the provisions, and are useful for structuring the key messages from the discussion.

There was no support for the distribution of prescription drugs directly to consumers, but some support for the distribution of samples for non-prescription and over-the-counter drugs.

Participants agree that:

- **Public safety should be a priority.**
- **Control should be commensurate with risk.** High risk products, or those where drug resistance could develop, should not be sampled directly to the public. There are divergent views as to whether sampling to health practitioners should continue for certain products. Products of lower risk could be distributed to health practitioners, but not to the public. There is more support for allowing the sampling of low-risk products to the public, such as sunscreen, for which evidence of therapeutic benefits exists. Some parties support including limitations on size in the definition of sample, as a way of minimizing potential risks.

## 5.2 **Option 2 Allow, and establish guidelines to control the distribution of drug samples to and by qualified health practitioners.**

Most participants support this option provided that the provisions include:

- Clear definition of qualified health practitioner;
- Clear definition of sample, including sample size, which may vary according to the product.

Key concerns:

- **Public safety.** Participants are concerned about public safety, particularly in the case of samples falling into the hands of children.
- **Distribution by pharmacists.** There is mixed support for the distribution of prescription drug samples by pharmacists. Those opposed argue that:
  - There is no documentation and, therefore, no way to address such issues as efficacy, side effects or product recall;
  - Pharmacists do not know the full patient history;
  - People can deal with more than one pharmacy and more than one doctor, with no or little communication between them;
  - Product recall may not reach consumers.

Those in favour note that many Canadians are without a family physician and guidelines could be developed to deal with the concerns.

- **Documentation.** It was suggested that samples could be documented at the level of the pharmacist to avoid drug interactions. The New Brunswick smart card model is an example of a way of distributing and monitoring the use of health products. However, the sampling card has drawbacks, including access to information concerns and potential for-profit use.

- **Vulnerable populations.** Although the purpose of drug sampling is not to address poverty problems, there was some support for the distribution by doctors of prescription drug samples to patients deemed vulnerable – low income, unemployed, students, and new Canadians.
- **Quality of samples.** Participants noted that samples are often distributed without regard to shelf life, contamination, or storage conditions including exposure to extreme temperatures. However, these concerns could be dealt with via guidelines.
- **Provision of information.** Participants focused on the need for clear information about drugs. They referred to models, which might be helpful, such as:
  - UK: A unique symbol is used to identify a new drug, an independent drug bulletin and public financing of timely information
  - Canadian Medical Association (CMA) web site: This provides a wealth of information to doctors and others.

Health Canada could provide current, up-to-date information in various ways, including a 1-800 number, electronic database, and Internet site.

- **Labeling.** There is concern that samples be clearly labeled to prevent resale or trade.
- **Relation between sampling and prescriptions.** There was also concern that samples may drive up the number of prescriptions for a given drug. In addition, samples are often for new products only and, therefore, may not be the treatment of choice. Controls in the guidelines should address this.

Other concerns included:

- Inequitable distribution;
- Whether the sample constitutes the most appropriate therapy;
- Potential conflict of interest of the doctor;
- Waste: Many samples are discarded, increasing environmental risks.

### **5.3 Option 3 Allow sampling of certain types of health products, which contribute positively to public health.**

Most participants support the distribution of over-the-counter drugs in the area of prevention and improving health, and for low risk products, such as sunscreen.

Some raised concerns about sampling directed to low-income individuals: When the sample runs out, these individuals may not have the resources to continue using a product that was shown to have a beneficial effect. This may not be only a question of sampling, but one of access to adequate health care, one of the principles of the Canada Health Act.

### **5.4 Option 4 Allow distribution of cosmetic samples.**

There was little discussion of this option. Questions raised include whether to allow samples of multivitamins to women, toothpaste, foods with health claims such as infant formula, and cereals with health claims.

## 5.5 Conclusions

While there was no agreement about whether or not sampling should be allowed, all participants agree that if it were allowed, some controls and restrictions would be necessary.

Moreover, participants agree that the definition of sample needs to be clarified in the context of the definitions of advertising and promotion, although there was no agreement about how it should be defined and by whom.

## 6. HEALTH PRACTITIONER ORIENTED PROMOTION

The legislative proposal with respect to health practitioner oriented promotion aims to:

- Restrict the promotion of health products to health professionals by regulation
- Help develop parameters for promotional activities directed to health professionals, possibly including a code of conduct regarding the relationship between health professionals and the pharmaceutical industry.<sup>14</sup>

Currently, any guidelines for health practitioner oriented promotion are handled by health practitioner associations, pharmaceutical associations or provincial licensing bodies. These are voluntary and not harmonized. Some have been established at a national level and others at provincial levels.

### 6.1 Areas of convergence

Participants agree on the following areas:

- **Restrict promotion.** Participants generally agree on the need to restrict promotion of health products to health care practitioners, with some totally opposed to any forms of promotion. Some suggest that limits must be set.
- **Make incentives taxable.** Participants feel that promotion relies unduly on incentives and are concerned that current guidelines are not enforced. They feel that gifts and incentives (e.g., particularly significant incentives like trips) influence prescribing practices. They suggest that incentives become taxable benefits with a mandatory declaration of the monetary value of gifts.
- **Limit commercial influence on research.** In addition to concern over the influence of incentives on prescribing practices, some participants express concern over the potential for commercial influence on research and on research agendas. It was suggested that this warrants further consideration.
- **Clearly distinguish between promotion and education.** Participants recognize that continuing education is a requirement for health professionals. They also recognize that much continuing education is currently sponsored by pharmaceutical industries, with no oversight of curriculum content, and is effectively promotion. They suggest that multi-sponsorship may help to neutralize

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<sup>14</sup> *ibid.*, 93.

such promotion. However, they feel it is important, in any case, to distinguish clearly between promotion and education.

Participants recognize that it will be challenging to ensure that educational events or activities are not promotional endeavours. They also recognize the accreditation challenges related to these events and feel these must be addressed.

- **Ensure pre-clearance.** Participants support a mandatory pre-clearance system for all information communicated to health practitioners, including journals, educational meetings and web sites, perhaps reviewed against a code of practice. Recognizing that this is currently outside of Health Canada's purview, it remains to be determined who would do this and how.
- **Provide independent information for health practitioners.** Participants want to ensure that health practitioners have access to neutral information and question whether the pharmaceutical industry can provide it. The Compendium of Pharmaceuticals and Specialties (CPS) is not considered neutral; other models were noted, such as the British National Formulary, which is free to health practitioners in the UK, and Australia's Medicines Handbook, which, while not free, is independently developed and owned by three professional organizations.
- **Establish independent body.** Once again, participants see the need for an independent body - broadly constituted and with consumer representation - to provide continuing medical education and academic detailing (or, at least, to ensure that it is neutral and balanced). Some suggest that such a body might be adapted from such existing bodies as the Pharmaceutical Advertising Advisory Board (PAAB) and Canada's Research-based Pharmaceutical Companies (RX&D). Others suggest that the model of the Canadian Radio-television and Telecommunications Commission (CRTC) be explored.
- **Establish, by regulation, a code of conduct.** Many participants feel that self-regulation is not working, and want a regulatory system to ensure that guidelines are met. They would like one clear regulatory code of conduct to govern the relationship between health professionals (including medical students) and the pharmaceutical industry, the principles of which would be endorsed by Health Canada. This could draw from and harmonize currently existing codes, including those of RX&D, CMA, and Canadian Pharmacists Association (CPA). Participants suggest that Health Canada can play an important convening role for the purpose of setting standards and establishing guidelines or regulations. They suggest that the code include:
  - Clear principles and expectations
  - National standards for marketing and promotional practices, developed in conjunction with provinces
  - Effective monitoring and enforcement
  - Transparent complaints process
  - Meaningful sanctions for violations
- **A weakness.** Some participants noted a weakness in the proposal, in that it does not deal with the economic implications of these practices and their implications for health care at a higher level. As well, there is a need to clearly define "health practitioner."

## 6.2 Conclusions

Overall, participants agree on the need for a set of binding rules to govern the promotion of health products to health practitioners and to distinguish promotion from continuing education. Further, these rules should be pre-cleared, monitored and enforced by an independent body whose prime motivation is public health and safety.

## 7. OVERALL CONCLUSIONS

The three consultations on advertising focused on deception, direct-to-consumer advertising, Schedule A, distribution of drug samples and health practitioner oriented promotion. The consultations allowed for in-depth discussion among a wide range of stakeholders, as well as good discussion between stakeholders and Health Canada officials.

### 7.1 Legislative provisions

With respect to the legislative proposal and its provisions, participants' discussions highlighted a number of key points:

- **Eliminate deception.** Participants agree with the intent of the proposal on deception. They want less vagueness, greater clarity and valid data. They want to strengthen rather than weaken the current situation. There are also divergent views regarding where the burden of proof should lie, and which body should be mandated to carry out monitoring and enforcement activities.
- **Develop a solution for drug advertising adapted to the Canadian situation and promote Direct-to-Consumer Information and Direct-to-Consumer Education (as opposed to advertising):** The current system is untenable. There was no agreement on whether or not to allow advertising for prescription drugs. Whichever tool is used to control Direct-to-Consumer Advertising (DTCA), it should ensure access to balanced information based on valid data for health practitioners and for consumers. Participants also support effective, transparent and timely monitoring and enforcement. However, there were divergent views about controls and whether controlled advertising/promotion is only marketing or whether it could be one mechanism to disseminate information.
- **Adapt Schedule A.** Most participants agree that Schedule A must be retained and reinforced. However, it needs updating, along with clear criteria and a transparent process for doing so. Participants feel that updating should be undertaken by an independent and broad-based advisory committee which includes consumers and health practitioners. However, there were divergent views about the criteria and process for updating Schedule A and the appropriate body to oversee this.
- **Regulate Sampling.** While there was no agreement about whether or not sampling should be allowed, all participants agree that if it were allowed, some controls and restrictions would be necessary. Participants did not reach agreement about whether or not sampling should continue to be allowed to health practitioners or whether some sampling should be allowed directly to the public. If the distribution of samples to health practitioners continues, controls and restrictions are needed. Moreover, participants agree that the definition of sample needs to be clarified, in the context of the definitions of advertising and promotion, although there was no agreement about how it should be defined and by whom.

- **Control health practitioner oriented promotion.** Participants expressed divergent views about whether promotion to health practitioners should be permitted. There was general support for distinguishing between promotion and information/education and controlling the content. Controls could take the form of a code of conduct, with a set of binding rules which should be monitored and enforced and perhaps pre-cleared by an independent body.

## 7.2 Approach

Participants also identified elements of the approach that Health Canada should take as it moves forward to develop its legislative proposal and associated regulations:

- **Clarify and tighten definitions,** such as deception, monitoring, enforcement, advertising, promotion, sampling and health practitioner.
- **Role for independent third party bodies.** Many participants see a role for independent bodies in overseeing key aspects of advertising of health products. These bodies must be balanced overall, and include consumer as well as health practitioner representation.
- **Monitor and enforce.** Participants want to ensure that any new legislation and regulation will include clear and effective enforcement mechanisms with meaningful sanctions.
- **Transparency is essential.** There is a need for transparency in the development and dissemination of information, as well as regarding compliance and enforcement.

## 7.3 Concluding messages

To summarize, the following messages were received across all three workshops:

- **The status quo is not tenable.** Existing provisions are out of date. Current sanctions are inadequate, as are monitoring and enforcement.
- **Better information is needed.** Consumers and practitioners need and deserve clear, balanced and neutral information in order to make informed choices about their health or that of their patients. Information should be based on valid data and presented in a balanced manner with adequate reference to the benefits and risks. Many participants consider that advertising is not information since its purpose is to promote sales.
- **Greater control is needed.** Greater control is needed over advertising than now presently exists. However, there are differences over what advertising to control and how. Canada should not follow the U.S. model but requires a solution adapted to the needs of Canadians. If drug advertising is allowed, it should be subject to meaningful controls including pre-clearance of the proposed promotion.
- **Health and safety is the highest priority.** The priority of any new health protection legislation must be the health and safety of Canadians. If and when advertising is allowed, it should be controlled and restricted to ensure that it contributes to the health and safety of Canadians.
- **There is an important role for Health Canada.** Health Canada must maintain a strong role in setting policy and guiding legislation.

## APPENDIX A - AGENDA

### Day one

- 8h30 - 9h00 Welcome and Purpose of the Session  
Review of Agenda and Approach  
Participant Introductions and Expectations
- 9h00 - 9h45 Health Canada Presentation:
- Legislative Renewal Consultation Process
  - Thematic Consultations: Advertising
- 9h45 - 9h55 Health Canada presentation on **Deception**
- 9h55-10h15 Questions and Answers to Clarify Understanding
- 10h15 - 10h30 Break**
- 10h30-11h00 Small Group Discussions on Deception
- 11h00-11h30 Plenary reporting: Areas of Convergence / Divergence
- 11h30-12h00 Health Canada presentations on **DTCA** tools in the Proposal
- 12h00 - 12h30 Questions and Answers to Clarify Understanding
- 12h30 - 13h30 Lunch**
- 13h30 - 15h30 Small Group Discussion on DTCA: Tools 1 to 4
- 15h30 - 15h45 Break**
- 15h45 - 16h45 Plenary reporting: Areas of Convergence / Divergence
- 16h45 - 17h00 Wrap up



## **Day 2**

8h30 - 8h45	Review of Day 2 agenda Summary of Day 1: Key messages on DTCA
8h45- 9h00	Health Canada presentation on options in the Proposal for <b>Schedule A</b>
9h00 -9h30	Questions and Answers to Clarify Understanding
9h30 - 10h15	Small Group Discussion on Schedule A: Options 1, 2 & 3
<b>10h15 -10h30 Break</b>	
10h30 - 11h15	Small Group Discussion on Schedule A: Options 1, 2 & 3 continued
11h15 - 12h00	Plenary reporting: Areas of Convergence / Divergence
<b>12h00 - 13h00 Lunch</b>	
13h00 - 13h15	Health Canada presentation on the proposed framework to regulate the <i>Distribution of Samples</i>
13h15 - 13h30	Questions and Answers to Clarify Understanding
13h30 - 13h45	Health Canada presentation on the proposed framework to regulate <i>Health Practitioner Oriented Promotion</i>
13h45 - 14h00	Questions and Answers to Clarify Understanding
14h00 - 14h45	Small Group Discussion: Distribution of Samples and Health Practitioner Oriented Promotion
<b>14h45 -15h00 Break</b>	
15h00 -15h45	Small Group Discussion continued: Distribution of Samples and Health Practitioner Oriented Promotion
15h45 -16h15	Plenary reporting: Areas of Convergence / Divergence
16h15 - 16h25	Evaluation
16h25 -16h35	Wrap up, next steps

## APPENDIX B - PARTICIPANTS

### Montreal, November 20-21

Linda J. Nagel	Advertising Standards Canada / Les normes canadiennes de la publicité
Joseph Mullie	Association of Quebec Advertising Agencies / L'Association des agences de publicité du Québec
Lysanne Grégoire	L'Association pour la santé publique du Québec
Terry Pigeon	Canadian AIDS Treatment Information Exchange / Réseau canadien d'infotraitements sida
Sandra Graham	Canadian Association of Broadcasters / L'Association canadienne des radiodiffuseurs
Michel Bergeron	Canadian Association of Health Sciences Editors / Association canadienne des rédacteurs en science de la santé
Harvey Lepine	Canadian Association of Medical Publishers / L'Association des éditeurs médicaux du Canada
Yves Millette	Canadian Life and Health Insurance Association Inc./ Association canadienne des compagnies d'assurances de personnes inc.
Barbara Mintzes	Center for Health Services and Policy Research, University of British Columbia
Paul Saba	Coalition of Physicians for Social Justice/ Coalition des médecins pour la justice sociale
Marie Pelchat	Coalition Solidarité Santé
Francine Cabana	Canadian Religious Conference /Conférence religieuse canadienne
Eric Racine	Groupe de recherche en Bio-Ethique, Université de Montréal / University of Montreal
Louise Roy	Le médecin du Québec
Laurette Dubé	McGill University. Faculty of Management / Université McGill. Faculté de gestion
Mickaël Ricquart	Option Consommateurs
Ray Chepesiuk	Pharmaceutical Advertising Advisory Board / Conseil consultatif de publicité pharmaceutique
André Senikas	Quebec Medical Association / Association médicale du Québec

Robert B. White	Nonprescription Drug Manufacturers Association of Canada / L'Association canadienne de l'industrie des médicaments en vente libre
Lise Lamontagne	Quebec Women's Health Action Network / Réseau québécois d' action pour la santé des femmes
Charles Tanguay	L'Union des consommateurs
Claudine Laurier	University of Montreal. Faculty of Pharmacy / Université de Montréal. Faculté de pharmacie

## **Toronto, November 27 – 28**

Al Gorlick	Alliance of Seniors to Protect Canada's Social Program / Alliance des personnes âgées pour la protection des programmes sociaux du Canada
Robert Rhéaume	Association of Canadian Advertisers (ACA) / Association canadienne des annonceurs
Mark Spurr	Association of Medical Advertising Agencies / Association des agences de publicité médicale du Canada
Denis Morrice	Best Medicines Coalition / Coalition pour de meilleurs médicaments
Gisela Mackay	By design e-Lab
Kevin Murray	Canada's Medical Device Technology Companies-MEDEC / Les sociétés canadiennes de technologie des dispositifs médicaux
Jean Szkotnicki	Canadian Animal Health Institute (CAHI) / L'Institut canadien de santé animale (ICSA)
David Chown	Canadian Association of Chain Drug Stores / L'Association canadienne des chaînes de pharmacies (CACDS)
Holly Vengroff	Canadian Association of Retired Persons (CARP) / Association canadienne des individus retraités
Heather Logan	Canadian Cancer Society / Société canadienne du cancer
Carl Carter	Canadian Cosmetic, Toiletry & Fragrance Association / L'Association canadienne des cosmétiques, produits de toilette et parfums (CCTFA)
Jeff Connell	Canadian Generic Pharmaceutical Association / L'Association canadienne du médicament générique
Penelope Marrett	Canadian Mental Health Association / L'Association canadienne pour la santé mentale

Shawn O'Reilly / Paul Saunders	Canadian Naturopathic Association / Association canadienne du naturopathie
Anne P. Kothawala / Terry Fallis	Canadian Newspaper Association / Association canadienne des journaux
Mary-Jo Makarchuk	Canadian Public Health Association (CPHA) / L'Association canadienne de santé publique
Shinya Ito	Canadian Society for Clinical Pharmacology / La Société canadienne de pharmacologie clinique (SCPC)
Philip Lundrigan	Canadian Treatment Action Council / Conseil canadien de surveillance et d'accès aux traitements (CCSAT)
Durhane Wong-Rieger	Consumer Advocare Network / Réseau des consommateurs AdvoCare
Joan Sayer	Consumer Association of Canada / Association des consommateurs du Canada
David Gardner	Dalhousie University / Université de Dalhousie
Terrence Young	Drug Safety Canada
Susan Bowyer / Barbara Martinez	Employers Committee on Health Care in Ontario
Carolyn O'Brien	Food and Consumer Products Manufacturers of Canada / Fabricants de produits alimentaires et de consommation du Canada
Elizabeth Sterken	INFACT Canada
Jani Yates	Institute of Communications and Advertising
Jim Everson	Magazines Canada
Claire Bombardier	University of Toronto / Université de Toronto
Joel Lexchin	York University / Université York

## **Ottawa, December 4 –5**

Claudine Pyke	Congress of National Seniors Organizations / Le congrès des organismes nationaux d'aînés
Bill Jeffery	Centre for Science in the Public Interest (Canada) / Centre pour la science dans l'intérêt public (Canada)
Dawn Burnett	Health Action Lobby (Heal) / Le groupe d'intervention action santé
Michael McBane	Canadian Health Coalition / Coalition canadienne de la santé

Bruce Squires	World Association of Medical Editors / Association mondial des éditeurs médicaux
Michelle Albagli	Canadian Dermatology Association / Association canadienne de dermatologie
Barbara Wells	National Association of Pharmacy Regulatory Authorities / Association nationale des organismes de réglementation de la pharmacie
Gordon Harrison	Canadian Homeopathic Pharmaceutical Association / Association pharmaceutique homéopathique du Canada
Millicent Toombs	Canadian Medical Association / Association médicale canadienne
Janet Davies	Canadian Nurses Association / Association des infirmières et des infirmiers du Canada
Gordon Dittberner	Canadian Veterinary Medical Association / Association canadienne des médecins vétérinaires
Pierrette Léonard	Royal College of Physicians and Surgeons / Le collège royal des médecins et chirurgiens du Canada
Alex Saunders	Canadian Psychiatric Association / Association des psychiatres du Canada
Julie Latrémouille	Canada's Research-based Pharmaceutical Companies / Les compagnies pharmaceutiques du Canada
Réjean Bouchard	Dairy Farmers of Canada/ Producteurs laitiers du Canada
Sandra Graham	Alliance for Access to Medical Information/ Alliance pour l'accès à l'information médicale
Joel Taller	Canadian Health Food Association (CHFA) / Association canadienne des aliments de santé
Manuel Arango	Heart and Stroke Foundation / Fondation des maladies du Coeur
Roy West	Health Charities Council of Canada / Conseil canadiens des organismes bénévoles en santé
Ben Kozak	Canadian AIDS Society / Société canadienne du sida
Ann Qualman	Canadian Arthritis Patient Alliance / Alliance canadienne des arthritiques
Karen Philip	Canadian Diabetes Association / Association canadienne du diabète
Janet Cooper	Canadian Pharmacists Association / Association des pharmaciens du Canada

## Other Attendees:

Ian Alexander	Health Canada
Lauraine Bégin	Health Canada
André Bergeron	Health Canada
Julie Bernier	Health Canada
Lindsay Blaney	Health Canada
Marie-Josée Bolduc	Health Canada
Sylvie Cantin	Health Canada
Stephanie Charron	Health Canada
Alixandria Clymans	Health Canada
Denise Côté	Health Canada
Odette Dubois	Health Canada
Roger Farley	Health Canada
Ryan Knelsen	Health Canada
Gillian Mandel	Health Canada
Isabelle McLinton	Health Canada
Julie Pigeon	Health Canada
Christophe Roy	Health Canada
Mark Samadhin	Health Canada
Shari Silber	Health Canada
Mario Simard	Health Canada
Elizabeth Smith-Kawasaki	Health Canada
Ann Sztuke-Fournier	Health Canada
Janine Small	Health Canada
Claude Desaulniers	Canadian Food Inspection Agency
Dianne DelZotto	Canadian Food Inspection Agency
Elizabeth Eves	Canadian Food Inspection Agency
Rhea Reeve	Canadian Food Inspection Agency
Anne Kennedy	Agriculture and Agri-Food Canada
Miriam Wyman	Practicum
Sandra Zagon	Practicum
Kathleen Connelly	Intersol Consulting
Marc Valois	Intersol Consulting